

Office Action Summary

Application No.

10/789,562

Applicant(s)

MITTERER ET AL.

Examiner

HOPE A. ROBINSON

Art Unit

1652

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/003621.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date: 2/14/09
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response to the Office Action mailed on June 23, 2008 on November 26, 2008, is acknowledged.
2. Claims 17-20 and 22 are pending. Claim 17 is under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to "an isolated protein fraction comprising Factor VII:C substantially free of platelet agglutinating vWF activity obtained from a factor VIII/vWF-containing solution by cation exchange chromatograph and step-wise elution at a salt concentration of between >200mM and <300mM, wherein the factor VIII/vWF-containing

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solution is a cryoprecipitate, a supernatant or an extract of a recombinant cell culture". The claimed invention is not adequately described with respect to the recited "substantially free of a platelet agglutinating vWF activity". The specification discloses:

"[A]ccording to a further aspect, a factor VIII:C which is substantially free from platelet-agglutinating vWF activity, obtainable from a factor VIII/vWF-containing solution, is provided by means of cation exchange chromatography and step-wise elution at a salt concentration of between .gtoreq.200 mM and .ltoreq.300 mM" see paragraph [0035]; "[A]ccording to a further aspect, a purified preparation containing factor VIII/vWF-complex which particularly contains high-molecular vWF multimers, or factor VIII:C, substantially free from platelet agglutinating vWF activity, is provided" see paragraph "[0036] and "[A] further criterion for the purity and the low infectiousness of a product is also the absence of contaminating nucleic acids. The preparation according to the invention thus is substantially free from nucleic acids.

"Substantially" here means that the content of nucleic acids is .ltoreq.0.7, based on the ratio 260/280 nm. The nucleic acid may, however, also be quantitated according to a method, e.g., as has been described in EP 0 714 987 and EP 0 714 988" see paragraph [0038].

Note that the information provided in the specification is not limiting and does not define what is intended in the claimed invention to be "substantially free from platelet-agglutinating vWF activity". A skilled artisan cannot quantify what amount is construed as "substantially free" and the disclosure does not breathe life into the claim with a limiting definition. The specification repeats the phrase recited in the claim, however, does not define the phrase to inform a skilled artisan of a measurable amount to practice the claimed invention and determine that applicant's are in possession of the product as claimed.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed invention. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim17 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 17 is indefinite for the recitation of "substantially free" because it is unclear what amount is "substantial". The metes and bounds of the claimed invention is undefined as the instant specification does not provide a limiting definition to breathe life into the claim.

Response to Arguments

5. Applicant's response has been considered. Note that the rejection of record is withdrawn based on applicant's comments. Upon due reconsideration the language of "substantially free" is rejected under 35 USC 112 first and second paragraphs as set forth above. This language has been previously discussed with applicant's representative and the disclosure in the specification was pointed to, however, it is not sufficient to breathe life into the claim language as stated above. The instant specification provides support for the phrase but does not adequately define the metes and bounds of the invention with respect to this phrase. A skilled artisan is left wondering how much is "substantially free". Based on the lack of guidance in the specification, the claimed invention lacks adequate written description to demonstrate possession of the invention as claimed. Clarification of the claim language is needed.

Conclusion

6. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30 from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652